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TRANSMITTAL FORM

Application Serial Number	09/666,452
Filing Date	September 21, 2000
First Named Inventor	Kleshinski
Patent No.	6,939,361
Issue Date	September 6, 2005
Attorney Docket No.	NMT-010CP2

Certificate SEP 2 8 2005 of Correction

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Check Attached
  - ☐ Copy of Fee Transmittal Form
- ☐ Amendment/Response
  - ☐ Preliminary
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
  - ☐ Letter to Official Draftsperson

  including Drawings [Total Sheets _____]
- ☐ Petition for Extension of Time
- ☐ Information Disclosure Statement
  - ☐ Form PTO-1449
  - ☐ Copies of IDS Citations
- ☐ Certified Copy of Priority Document(s)
- ☐ Sequence Listing submission
  - ☐ Paper Copy/CD
  - ☐ Computer Readable Copy
  - ☐ Statement verifying identity of above
- ☐ Copy of Notice to File Missing Parts of Application
- ☐ Formal Drawing(s)
- ☐ Request For Continued Examination (RCE) Transmittal
- ☐ Power of Attorney By Assignee of Entire Interest/Revocation of Prior Powers and New Power of Attorney
- ☐ Terminal Disclaimer
- ☐ Executed Declaration and Power of Attorney for Utility or Design Patent Application
- ☐ Small Entity Statement
- ☐ CD(s) for large table or computer program
- ☐ Amendment After Allowance
- ☒ Request for Certificate of Correction (4 pages)
  - ☒ Certificate of Correction (Form PTO-1050) (1 page)
- ☐ Notice of Appeal to Board of Patent Appeals and Interferences
- ☐ Appeal Brief (in triplicate)
- ☐ Status Inquiry
- ☒ Return Receipt Postcard
- ☒ Certificate of First Class Mailing under 37 C.F.R. 1.8 (1 page)
- ☐ Certificate of Facsimile Transmission under 37 C.F.R. 1.8
- ☒ Additional Enclosure(s) *(please identify below)*

"Exhibit A" – Copy of U.S. Patent Application No. 09/666,452 Specification and Claims as originally filed on September 21, 2000, (22 pages), and a copy of the associated return-receipt postcard date-stamped September 21, 2000, (1 page)

"Exhibit B" – Copy of Preliminary Amendment filed September 24, 2003, (10 pages), and a copy of the associated return-receipt postcard date-stamped September 24, 2003, (1 page)

"Exhibit C" – Copy of Preliminary Amendment filed May 10, 2004, (12 pages), and a copy of the associated return-receipt postcard date-stamped May 10, 2004, (1 page)

CORRESPONDENCE ADDRESS

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Respectfully submitted,

Date: September 20, 2005
Reg. No. 44,244
Tel. No.: (617) 261-3167
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Ronda P. Moore, D.V.M.
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SEP 2 8 2005

BOS-897293 v1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	Kleshinski		
SERIAL NO.:	09/666,452	PATENT NO.:	6,939,361 B1
FILING DATE:	September 21, 2000	ISSUE DATE:	September 6, 2005
TITLE:	Guidewire For a Free Standing Intervascular Device Having an Integral Stop Mechanism		

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any documents referred to as enclosed herein, are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to ATTN: Certificate of Correction Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 20th day of September, 2005.

Brenda L. MacLean

Attn: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith are:

1. Transmittal Form (1 page);
2. Request for Certificate of Correction (4 pages);
3. Certificate of Correction (Form PTO-1050) (1 page);
4. "Exhibit A" – Copy of U.S. Patent Application No. 09/666,452 Specification and Claims as originally filed on September 21, 2000, (22 pages), and a copy of the associated return-receipt postcard date-stamped September 21, 2000, (1 page);
5. "Exhibit B" – Copy of Preliminary Amendment filed September 24, 2003, (10 pages), and a copy of the associated return-receipt postcard date-stamped September 24, 2003, (1 page);
6. "Exhibit C" – Copy of Preliminary Amendment filed May 10, 2004, (12 pages), and a copy of the associated return-receipt postcard date-stamped May 10, 2004, (1 page); and
7. a return receipt postcard.

PTO/SB/44 (04-05)
Approved for use through 04/30/2007. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,939,361 B1

APPLICATION NO.: 09/666,452

ISSUE DATE : September 6, 2005

INVENTOR(S) : Kleshinski et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 9, line 20, replace the word "tow" with --two--.

In claim 11, at line 31, after the words 'formed to bias' insert the word --said--.

In claim 15, at line 46, after the words 'barb being formed' insert the word --to--.

In claim 19, at line 28, replace the word "wall" with --walled--.

In claim 20, at line 43, replace the word "position" with --positions--.

In claim 24, at line 63, replace "claim 24" with --claim 23--.

In claim 30, at line 30, replace "intravasculr" with --intravascular--.

In claim 30, at line 33, between 'dimension' and 'of said channel' insert --which is greater than the inner dimension of said channel but less than an outer dimension--.

In claim 44, at line 20, after the words 'formed to bias' insert the word --said--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Patent Administrator
Kirkpatrick & Lockhart Nicholson Graham LLP
75 State St., Boston, MA 02109-1808 (617) 261-3100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

INVENTOR:	Kleshinski
PATENT NO.:	6,939,361 B1
ISSUE DATE:	September 6, 2005
SERIAL NO.:	09/666,452
FILING DATE.:	September 21, 2000
TITLE:	Guidewire for a Free Standing Intervascular Device Having an Integral Stop Mechanism

ATTN: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION

Dear Sir:

The Assignee of record of the above-identified patent, NMT Medical, Inc., by virtue, at least, of an assignment recorded in the U.S. Patent and Trademark Office (USPTO) on March 13, 2001, at Reel No. 011631, Frame No. 0589, hereby requests that a Certificate of Correction be issued for U.S. Patent No. 6,939,361 under 35 U.S.C. § 254 and 37 C.F.R. § 1.322.

The Assignee requests the correction of errors in the listing of the claims. In particular, the assignee requests correction of typographical errors and omissions in issued claims 9, 11, 15, 19, 20, 24, 30, and 44.

The errors in issued claims 9, 11, 15, 19, 20 and 24 are evident in light of the claims originally filed on September 21, 2000. Applicants attach as "Exhibit A" a copy of the application, including the claims, as originally filed, along with the date-stamped return receipt postcard indicating that the originally filed claims were in fact received by the USPTO. The Assignee submits that no amendments were made after the submission of the original claim set that would be inconsistent with the corrections requested.

Issued claim 9 corresponds to originally filed claim 10. Issued claim 9 appears in column 10, and at line 20 recites "comprises tow opposed openings... ." As shown in Exhibit A, original

claim 10 recites "comprising two opposed openings... ." The Assignee submits that "tow" is a typographical error by the USPTO and should be replaced with "two" in issued claim 9.

Issued claim 11 corresponds to original claim 12. Issued claim 11 appears in column 10, and at line 31 recites "formed to bias boss element... ." As shown in Exhibit A, original claim 12 recites "formed to bias said boss element... ." The Assignee submits that "said" was omitted by the USPTO and should be inserted into issued claim 11.

Issued claim 15 corresponds to original claim 16. Issued claim 15 appears in column 10, and at line 46 recites "barb being formed normally extend... ." As shown in Exhibit A, original claim 16 recites "barb being formed to normally extend... ." The Assignee submits that "to" was omitted by the USPTO and should be inserted into issued claim 15.

Issued claim 19 corresponds to original claim 20. Issued claim 19 appears in column 11, and at line 28 recites "said thin wall body member... ." As shown in Exhibit A, original claim 20 recites "said thin walled body member... ." The Assignee submits that "wall" is a typographical error of the USPTO and should be replaced with "walled" in issued claim 19.

Issued claim 20 corresponds to original claim 21. Issued claim 20 appears in column 11, and at line 43 recites "expanded position." As shown in Exhibit A, original claim 21 recites "expanded positions." The Assignee submits that "position" is a typographical error of the USPTO and should therefore be replaced with "positions" in issued claim 20.

Issued claim 24 corresponds to original claim 25. Issued claim 24 appears in column 11, and at line 63 recites a dependency to claim 24. Therefore, on its face, issued claim 24 is dependent upon itself. However, as shown in Exhibit A, original claim 25 is not dependent on itself but, rather, is dependent on original claim 24. Original claim 24 now corresponds to issued claim 23. The Assignee therefore submits that for issued claim 24, "The guidewire of claim 24..." at column 11, line 63, should be replaced with "The guidewire of claim 23... ." Applicants submit that the USPTO made an error in renumbering the dependencies in the published patent.

Errors in issued claim 30 and 44 are evident in light of a Preliminary Amendment submitted to the USPTO on September 24, 2003. A copy of the Preliminary Amendment, along with a copy of the date-stamped return-receipt postcard, indicating receipt by the USPTO of the Preliminary Amendment, is attached as "Exhibit B." Because the Preliminary Amendment was

submitted in conjunction with a Request for Continued Examination, it should have been entered by the Examiner.

Issued claim 30 corresponds to newly introduced claim 29 in the September 24, 2003, Preliminary Amendment. Issued claim 30 appears in column 12, and at line 30 recites "said intervasculr (sic) device... ." As shown in Exhibit B, original claim 29 recites "said intervascular device... ." The Assignee submits that "intervasculr" was spelled incorrectly by the USPTO and should be replaced by "intervascular" in issued claim 30.

Issued claim 44 corresponds to newly introduced claim 39 appearing in the Preliminary Amendment. Issued claim 44 appears in column 14, and at line 20 recites "to bias boss element... ." As shown in Exhibit B, claim 39 recites "to bias said boss element... ." The Assignee submits that "said" was omitted by the USPTO and should be appropriately inserted into issued claim 44.

A further error in issued claim 30 is evident in light of the claims submitted to the USPTO in a Preliminary Amendment on May 10, 2004. A copy of the Preliminary Amendment, along with a copy of the date-stamped return-receipt postcard indicating receipt of the Preliminary Amendment by the USPTO is attached as "Exhibit C." Because the Preliminary Amendment was submitted in conjunction with a Request for Continued Examination, it should have been entered by the Examiner.

Issued claim 30 corresponds to claim 29 appearing in the Preliminary Amendment. Issued claim 30 appears in column 12, and at lines 32-33 recites "to comprise an outer dimension of said intervascular device... ." However, as shown in Exhibit C, amended claim 29 recites "to comprise an outer dimension which is greater than the inner dimension of said channel but less than an outer dimension of said intervascular device... ." The Assignee submits that the underlined passage was omitted by the USPTO and should be inserted into issued claim 30.

In view of the above, the Assignee respectfully submits that the errors in U.S. Patent No. 6,939,361 are due to a Patent Office mistake and are therefore correctable pursuant to 35 U.S.C. § 1.322.

A copy of a computer generated Form PTO-1050 is enclosed. The Assignee believes that the enclosed Form PTO-1050 corrects the errors in issued claims 9, 11, 15, 19, 20, 24, 30, and 44. The following is a summary of the content of the enclosed Form PTO-1050:

In claim 9, line 20, replace the word "tow" with --two--.

In claim 11, at line 31, after the words 'formed to bias' insert the word --said--.

In claim 15, at line 46, after the words 'barb being formed' insert the word --to--.

In claim 19, at line 28, replace the word "wall" with --walled--.

In claim 20, at line 43, replace the word "position" with --positions--.

In claim 24, at line 63, replace "claim 24" with --claim 23--.

In claim 30, at line 30, replace "intravasculr" with --intravascular--.

In claim 30, at line 33, between 'dimension' and 'of said channel' insert --which is greater than the inner dimension of said channel but less than an outer dimension--.

In claim 44, at line 20, after the words 'formed to bias' insert the word --said--.

The Assignee believes that the errors described above warrant issuance of a certificate of Correction for U.S. Patent No. 6,939,361. Accordingly, the Assignee encloses the aforementioned Form PTO-1050 to correct the errors in the above-identified patent and requests that the Commissioner issue a Certificate of Correction reflecting the changes to U.S. Patent No. 6,939,361 as they appear on the enclosed Form PTO-1050.

The Assignee believes no fee is necessitated by this Request for a Certificate of Correction as the errors apparently arose due to a Patent Office mistake. If a fee is nevertheless due, please charge Attorney's Deposit Account No. 50-1721. The Patent Office is invited to call the undersigned attorney with any questions concerning submission of this paper.

Respectfully submitted,

Ronda P. Moore, D.V.M.

Date: September 20, 2005
Reg. No. 44,244

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BOS-896710 v1

EXHIBIT A

COPY

This will acknowledge receipt in re filing a Continuation-in-Part Application based on Provisional Application SN 60/155,090:

1. Utility Patent Application Transmittal
2. Specification, Claims, Abstract (23 pages)
3. Four (4) sheets of drawings (Figs. 1-8)
4. Unexecuted Declaration and Power of Attorney

in re new PATENT application based on Provisional SN 60/155,090:
Stephen J. Kleshinski
For: GUIDEWIRE FOR A FREE STANDING INTERVASCULAR DEVICE HAVING AN INTEGRAL STOP MECHANISM

Docket: 0984-203
DWS/sys

September 21, 2000
Hand delivered

PLEASE STAMP WITH SERIAL NO. AND RETURN

EXHIBIT A

COPY

GUIDEWIRE FOR A FREE STANDING INTERVASCULAR DEVICE HAVING AN INTEGRAL STOP MECHANISM

This application is a continuation-in-part application of copending U.S. Serial No. 09/360,654 filed July 26, 1999 and is based upon U.S. Provisional Patent Application Serial No. 60/155,090 filed September 22, 1999.

Technical Field

The present invention relates generally to a guidewire for positioning and removing emboli capture and recovery devices (ECRD) such as small filters in a vein or artery, and more particularly to a guidewire with an integral stop mechanism which, when expanded or extended, permits the guide wire to move freely with respect to the filter while preventing the guidewire from being inadvertently removed from association with the filter and when collapsed or retracted permits the guidewire to be inserted through or removed from the filter.

Background of the Invention

In recent years, a number of intervascular medical devices have been designed which are adapted for compression into a small size to facilitate introduction into a body vessel such as an arterial or vascular passageway and which are subsequently expandable into contact with walls of the passageway. These devices, among others, include stents, such as those shown by U.S. Patent No 5,540,712 and blood clot filters such as those shown by U.S. Patent No. 5,669,933 which expand and are held in position by engagement with the inner wall of a vessel. It has been found to be advantageous to form such devices of a thermal shape memory material having a first,

relatively pliable low temperature condition and a second, relatively rigid high-temperature condition. By forming such devices of temperature responsive material, the device in a flexible and reduced stress state may be compressed to fit within the bore of a delivery catheter when exposed to a temperature below a predetermined transition temperature, but at temperatures at or above the transition temperature, the device expands and becomes relatively rigid.

Known self expanding medical devices have been formed of Nitinol, an alloy of titanium and nickel which provides the device with a thermal memory. The unique characteristic of this alloy is its thermally triggered shape memory, which allows a device constructed of the alloy to be cooled below a temperature transformation level to a martensitic state and thereby softened for loading into a catheter in a relatively compressed and elongated state, and to regain the memorized shape in an austenitic state when warmed to a selected temperature, above the temperature transformation level, such as human body temperature. The two interchangeable shapes are possible because of the two distinct microcrystalline structures that are interchangeable with a small variation in temperature. The temperature at which the device assumes its first configuration may be varied within wide limits by changing the composition of the alloy. Thus, while for human use the alloy may be focused on a transition temperature range close to 98.6°F, the alloy readily may be modified for use in animals with different body temperatures.

In recent years advances have been made in the treatment of blood vessel stenosis or occlusion by plaque, thrombi, embolic, or other deposits which adversely reduce or block the flow of blood through a vessel. Balloon angioplasty or similar transluminal treatments have become common for some blood vessel lesions, but for all such procedures, plaque and emboli dislodged during the procedure are free to flow within the lumen of the vessel and possibly cause substantial injury to a patient.

In an attempt to contain and remove emboli and other debris, balloon angioplasty coupled with irrigation and aspiration has been performed as illustrated by

U.S. Patent No. 5,883,644 and International Publication No. WO 98/39046 to Zadno-Azizi et al. This procedure requires complete vessel occlusion cutting off all blood flow which imposes severe time constraints on the procedure. Additionally, the balloons involved in the procedure are affixed to elongate guidewires or small elongate catheters which extend for a substantial distance through blood vessels to the location of the stenosis or occlusion, and it is practically impossible to prevent some back and forth longitudinal motion of these elongate elements within a vessel during a procedure. This movement of the guidewire or catheter to which a balloon is attached causes the balloon to move back and forth and abrade emboli from the vessel wall downstream of the balloon containment area.

Angioplasty is often not a preferred treatment for lesions in the carotid artery because dislodged plaque can enter arterial vessels of the brain causing brain damage or even death. As indicated by U.S. Patent No. 5,879,367 to Kaganov et al., carotid endarterectomy is a surgical procedure used to remove a lesion in the carotid artery, but this procedure also involves substantial risk of dislodged embolic material.

In an attempt to contain dislodged emboli during a procedure to clear blood vessel stenosis or occlusion, a variety of distal filters have been devised such as those shown by U.S. Patent No. 5,814,064 and International Publication Nos. WO 98/38920 and WO 98/39053 to Daniel et al. as well as U.S. Patent Nos. 5,827,324 to Cassell et al., 5,846,260 to Maahs and 5,876,367 to Kaganov et al. These filters are secured to the distal portion of a guidewire or catheter and are deployed distally from the stenosis or occlusion to capture embolic material. Once the distal filter is positioned and expanded into contact with the wall of the blood vessel, an angioplasty balloon, a stent, or other devices are introduced over the proximal end of the guidewire or catheter to which the filter is attached and moved into position in the area of the occlusion or stenosis spaced proximally from the filter.

Known guidewire or catheter attached distal filters have been subject to a number of disadvantages. First, since the elongate catheter or guidewire to which the

filter is attached is used to guide over the wire devices during a subsequent procedure, it is extremely difficult if not impossible to prevent longitudinal movement of the wire or catheter after the filter has been deployed. This causes the filter to move back and forth within the vessel with resultant abrasion by the filter of the vessel wall, and such abrasion not only causes trauma to the vessel wall but also operates to dislodge debris which is free to flow distally of the filter. Thus filter movement after the filter is deployed somewhat defeats the purpose of the filter. Also, it is often desirable during a procedure to exchange guidewires, and such an exchange is not possible with an attached filter.

Additionally, the retrieval of known distal filters while retaining captured embolic material has proven to be problematic. Many cone shaped filters with wide, upstream proximal open ends tend to eject captured embolic material through the open end as the filter is collapsed. Also, many distal filters are formed by a mesh material which is expanded by a filter frame, and when the frame closes to collapse the filter for withdrawal through a catheter, the mesh folds creating outwardly projecting pleats. These pleats snag on the withdrawal of the catheter making retrieval of the filter difficult and often causing the filter to spill captured embolic material.

Recently, it has become of concern that if the guidewire is made to be displaceable with respect to a filter or other intervascular device, there is the possibility that the device could become disassociated with the guidewire and consequently could migrate and become lost within the vessel. Accordingly, there is a need for a mechanism to provide selective association of the guidewire with a free standing, unsecured intervascular device when necessary while also being capable of stopping travel of the device away from the stenosis or occlusion in order to alleviate concerns regarding free migration of the device within a blood vessel.

Summary of the Invention

A primary object of the present invention is to provide a combination intervascular device and guidewire wherein the guidewire is longitudinally movable relative to the intervascular device.

It is an object of the present invention to provide a novel and improved guidewire for confidently positioning a free standing filter for expansion within a blood vessel to capture dislodged embolic material.

Another object of the present invention is to provide a novel and improved guidewire for confidently positioning a free standing filter for use during a procedure to treat blood vessel stenosis or occlusion which does not cause filter movement which results in trauma to the luminal wall during guidewire, balloon and stent exchanges and which can be associated with the filter in a manner to facilitate longitudinal movement of the guidewire relative to the filter while precluding filter migration.

A further object of the present invention is to provide a novel and improved guidewire for positioning a free standing filter for use during a procedure to treat blood vessel stenosis or occlusion which is formed to facilitate intra-procedural guidewire exchanges and which reduces concern for the disassociation of the filter from the guidewire during normal procedures.

Yet another object of the present invention is to provide a novel and improved guidewire for use with a free standing filter during a procedure to treat blood vessel stenosis or occlusion which is formed to remain stationary after expansion independent of guidewire or catheter motion which maintains an association with the filter to ensure proper removal of the filter upon completion of the procedure.

A still further object of the present invention is to provide a novel and improved guidewire for association with the positioning of ECRD including a stop mechanism in the area of a distal end thereof to expand or extend and collapse or retract on actuation thereby forming a mechanical stop preventing the guidewire from being inadvertently removed from the ECRD.

These and other objects of the present invention are accomplished by providing an elongated guidewire having a stop mechanism thereon which is receivable in a receiving member extending centrally through an intervascular device provided with an open-ended channel which may be configured to receive a plurality of different sized guidewires. The guidewire stop mechanism is positioned in the area of a distal end of the guidewire and may be selectively expanded or extended and collapsed or retracted to permit selective association with the intervascular device. When positioned through the receiving member of the intervascular device, the stop mechanism can be expanded or extended to prevent the loss of the device while still permitting the guidewire to move longitudinally with respect to the device. The stop mechanism may take on numerous configurations namely that of a balloon, a grappling hook, a buckled tube, a braided structure, barbs, biased bosses or any mechanism which is remotely expandable or extendable and collapsible or retractable from a guidewire. In the retracted position, the stop member should pass freely through the receiving member of the intervascular device, but in the expanded position, the stop member should be radially spaced from the inner wall of a blood vessel while precluding migration of the intervascular device over the distal end of the guidewire.

Brief Description of the Drawings

Figure 1 is a view in side elevation of the free standing filter which can readily accommodate the guidewire of the present invention in the expanded configuration having the guidewire in accordance with the present invention positioned therein with the stop member expanded;

Figure 2 is a partially sectional view in side elevation of a second free standing filter which can readily accommodate the guidewire of the present invention;

Figure 3 is a partially sectional view of the free standing filter of Figure 2 within a delivery tube having the guidewire in accordance with the present invention positioned therein with the stop member retracted;

Figure 4 is an expanded sectional view of a distal end of a guidewire in accordance with the present invention including a stop mechanism in the form of a balloon therein in an expanded condition;

Figure 5 is an expanded sectional view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of a grapple hook in an extended position;

Figure 6 is an expanded sectional view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of a buckled tube in an expanded condition;

Figure 7 is an expanded sectional view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of barbs in an extended position;

Figure 8 is an expanded view of a distal end of a guidewire in accordance with an alternative embodiment of the present invention including a stop mechanism in the form of a boss element in an extended position.

Description of the Preferred Embodiments

Referring to Figure 1, a free standing filter 10 which is suitable for accommodating the guidewire 12 in accordance with the present invention is formed

around a central tube 11 defining an open ended channel which forms the longitudinal axis for the filter 10 and which slidingly receives the guidewire 12. The frame of the filter is formed by a stent 14 which may be collapsed inwardly toward the tube 11 and which expands outwardly away from the tube to the substantially cylindrical open ended configuration shown in the drawings. Ideally, this stent is formed of thermal shape memory material and is of the type shown by U.S. Patent No. 5,540,712, although other expandable stents can be used. The stent 14 is coupled at one end to the central tube 11 by elongate lead wires 16 which extend between an open proximal end 18 of the stent and a spaced coupling 20 which is secured to the central tube 11. It should be readily appreciated by those skilled in the art that the guidewire 12 in accordance with present invention may be used in conjunction with any ECRD, stent, or other intervascular medical device sized for positioning in a body vessel such as an arterial or vascular passageway without departing from the spirit and scope of the present invention.

In the example illustrated in Figure 1, extending around the stent 14 and attached thereto is a flexible, fine mesh filter material 22 which opens at the proximal end 18 of the stent and covers the body of the stent. Ideally, the stent extends over this mesh filter material. At the distal end 24 of the stent, the fine mesh filter material projects outwardly to form a flexible conical section 26 with an apex 28 connected to a coupling 30 which slides on the tube 11 in spaced relation to the stent distal end 24. Thus when the stent expands as shown in the drawings, the mesh filter material forms a substantially cylindrical section 32 which opens at the proximal end of the stent and a flexible, closed conical section 26 which extends beyond the distal end of the stent to catch and collect small particles. The fine filter mesh may be formed of suitable biocompatible material such as polyester or a PTFE material and is coated with thromboresistant materials such as, for example, Phosphoral Choline or Hyaluronic Acid. The mesh is a braided material or elastomeric mesh which normally conforms to the exterior shape of the central tube 11, but which stretches to expand outwardly away from the tube when the stent 24 expands. Thus the mesh is biased toward the tube 11,

and when the stent collapses inwardly toward the tube, the mesh contracts back to the exterior shape of the tube and does not form pleats.

In the operation of the filter 10, the stent with the mesh filter material is inserted in a collapsed condition into a delivery tube 34 and guidewire 12 extends through the central tube 11. Then the delivery tube is used to deliver the filter 10 over the guidewire 12 to a desired position within a body vessel whereupon the filter is ejected from the delivery tube. Now the previously collapsed stent 14 expands into contact with the walls 36 of the vessel (shown in broken lines) thereby expanding the flexible mesh filter material which was previously collapsed within the delivery tube with the stent. The guidewire 12 may now be used to guide other devices into the vessel, and since the guidewire can move freely in a longitudinal direction within the tube 11, longitudinal movement of the guidewire will not result in movement of the expanded filter.

Once the stent 14 has expanded against the wall 36 of the vessel, the guidewire 12 can be removed and replaced with a new guidewire of a different size. The tube 11 is preferably formed with an internal dimension of sufficient size to accept .014 inch diameter to .035 inch diameter guidewires. It may often be desirable to initially use a very fine guidewire (.014") to cross a lesion and position the filter 10 and to then exchange this fine guidewire for a thicker wire. The details of the association of the guidewire with the tube 11 will be set forth in detail hereinbelow.

The fine mesh filter material 22, when expanded, should have a pore size within a range of 100 Mm to 150 Mm to capture and retain embolic material sized in excess of the pore size while permitting blood flow in the direction of the arrow 38 line in Figure 1 between the wires 16 and into the proximal end 18 of the stent 14. The blood and embolic material flows through the and into the flexible conical section 26 of the fine mesh filter material where the embolic material is trapped while the blood passes through the filter material.

To remove the filter 10 with the captured embolic material, the stent 14 is collapsed against the tube 11 for withdrawal through a catheter or delivery tube 34.

Preferably the stent is formed of the thermal shape memory material such as nitinol and may be collapsed by cooling the stent to a temperature below a transition temperature. It is important to note that the embolic material has been captured within the conical section 28, so that when the stent collapses against the tube 11, it positively closes the mouth of the conical section preventing material from escaping as the filter is drawn into the tube 34. The stent forces the entire longitudinal extent of the section 32 against the tube 11 to prevent the escape of material from the conical section 28.

The guidewire 12 has an elongate, flexible body 13 which extends from a distal end of the wire 15 to a proximal end 17 which projects beyond the proximal end of the catheter or delivery tube 34. Adjacent to the distal end 15 of the guidewire 12 is an expandable and contractable stop member 19 which moves between a contracted position adjacent to the guidewire and an expanded position as shown in Figure 1. In the contracted position of the stop member, the stop member is dimensioned to move freely with the guidewire 12 through the tube 11, but once through the tube, the stop member can be manually or automatically expanded to prevent migration of the filter over the distal end of the guidewire. In the expanded position, the stop member has an outer dimension which is larger than the internal dimension of the channel through the tube 11, but the outer dimension of the expanded stop member is radially spaced from the inner wall 36 of the blood vessel. This is important as contact by the stop member with the vessel wall would dislodge plaque downstream of the filter 10 as the guidewire moves during an intervascular procedure.

With the stop member 19 in the expanded position, the guidewire 12 can still move longitudinally relative to the filter 10, but may not be withdrawn from the filter nor may the filter migrate over the distal end of the guidewire. A number of stop member structures will subsequently be discussed, but the stop member could be formed of two or more short arms 21 and 23 secured at one end to the guidewire 12. These

arms can be constructed of spring metal or of nitinol so that they lie flat against the guidewire as it passes through the catheter 34 and spring outwardly as the guidewire and filter leave the catheter.

Referring now to Figures 2 and 3, a second example of a free standing filter which may readily accommodate the guidewire 12 in accordance with the present invention is indicated generally at 40. For unimpeded passage through a catheter or delivery tube 34, it is beneficial to form a filter with a frame which completely surrounds and protects the filter mesh material. Thus the filter 40 includes a cellular frame 42 which is preferably formed of thermal shape memory material such as nitinol, and this frame when expanded includes a central section 44 having a substantially tubular configuration, a proximal end section 46 and a distal end section 48, both having a substantially conical configuration. A central tube 50, similar in size and structure to the tube 11, forms the central longitudinal axis for the filter 40 and extends through the filter and outwardly from the proximal and distal sections of the frame 42. The distal end of the tube 50 is provided with a tapered atraumatic molded tip 52 configured to center and guide the filter within the delivery tube 34.

The central section 44 of the frame 42 includes a plurality of interconnected cells 54 which are substantially equal in size and which are defined by spaced sidewalls 56 and 58 which extend substantially parallel to the tube 50 and the longitudinal axis of the filter. Adjacent cells 54 in a row of cells extending around the central tube 50 are connected together by their adjacent sidewalls 56 and 58, and these sidewalls remain substantially parallel to the tube 50 in both the expanded and collapsed configuration of the filter 40 as illustrated in Figures 2 and 3. The opposite ends of each cell are formed by outwardly inclined endwall sections 60 and 62 which meet at an apex 64. Extending in a distal direction from the apex 64 of alternate cells 54 at the proximal end of the central section 44 are short, straight stabilizers 66 which engage the vessel wall

36 when the filter is expanded and aid to preclude movement of the filter in a distal direction.

The proximal end section 46 and distal end section 48 of the frame 42 are formed of cells 68 with tapered sidewalls 70 and 72 which extend at an angle to the central tube 50 to form the tapered conical end sections of the frame. Proximal end section 46 of the frame is secured to the tube 50 by a coupling 74, and distal end section 48 is secured to a coupling 76 which slides on the tube 50. The couplings 74 and 76 are provided with radiopaque markers 78 and 80 respectively.

Fine mesh filter material 82 of the type previously described for the filter 10 is positioned within the central and distal sections of the frame 42. This filter material is bonded to at least the first row of cells 54 in the proximal end of the central section 44 of the frame, and at the distal end of the frame the filter material is secured to the tube 50 adjacent to the coupling 76 by a coupling 84. Thus the filter material forms a cone when the filter 40 is expanded, and the open proximal end of the cone is positively closed when the proximal end row of cells of the central section 44 collapse against the tube 50.

As shown in Figure 3, when the filter 40 moves along the guidewire 12 through the delivery tube 34, the mesh filter material 82 is enclosed within the frame 42 which protects the filter material. Also, when an expanded filter is contracted and drawn back into the delivery tube, the frame engages the delivery tube and precludes the filter from catching or snagging on the delivery tube.

With reference now to Figure 4, an initial embodiment of the guidewire set forth in accordance with the present invention is illustrated therein. Figure 4 illustrates a distal end of the guidewire 12 which includes the stop mechanism 100 in the form of an elastic balloon mounted around the guidewire which is expandable and collapsible with respect to the guidewire 12. The guidewire defines an enclosed, central chamber 102 which extends from the proximal end of the guidewire to the stop mechanism 100 and through which air can be provided to expand the balloon. The balloon 110 is

expandable and collapsible with respect to the guidewire 12 by way of ports 112 and 114 which connect the interior of the balloon to the channel 102. As can be appreciated by one of ordinary skill in the art, when the balloon 110 of the guidewire 12 is expanded to a condition illustrated in Figure 4, a filter or other free standing intervascular device, if dislodged from a vessel during an angioplasty or other procedure, would be stopped by the stop mechanism 100 in that the balloon is expandable to a dimension greater than that of the tube 11 of the filter or device but to a dimension which is less than the fully expanded dimension of the intervascular device. Accordingly, the operation can confidently take place knowing that the filter or device will not become lost within the vessel. Further, in order to permit the exchange of guidewires as referred to hereinabove, the balloon is selectably collapsible so as to allow the guidewire 12 to be intentionally removed from the tube 11 in order to allow for exchange of guidewires.

With reference to Figures 5, 6, 7 and 8, various embodiments of the present invention are set forth. As noted from Figure 5, extendable and retractable grappling hooks 116 are mounted to slide within the channel 102 and are provided to form a positive stop which is extendable from the guidewire 12 for a sufficient radius so as to ensure that the tube 11 of the filter cannot pass thereby. The grappling hooks 116 may be extendable from the guidewire 12 in any known manner. For example, a flexible rod 117 slidable within the channel 102 and connected to the hook extensions 118 can move axially with respect to the guidewire 12 and permit the extension and retraction of the grappling hooks 116.

The grappling hooks 116 may be extended and retracted through openings 104 formed on opposite sides of the guidewire which open into the channel 102. The grappling hooks may be formed of spring metal strips which curl outwardly when the hooks are extended or may be formed of strips of thermal shape memory material such as nitinol having a temperature transition level such that the hooks curl to the configuration shown in Figure 5 when they are extended from the guidewire within a blood vessel. Again, the extended configuration of the hooks is such that they cannot

pass through the tube 11, but when fully extended, they do not extend to the extent of the extended position of the intervascular device through which the guidewire passes.

Alternatively, as illustrated in Figure 6, the stop mechanism 100 may take the configuration of a buckle tube 119 which is slidably mounted on the guidewire 12 but is attached to the guidewire at its distal end 121. When the tube 119 is displaced relative to the guidewire toward the distal end 106 of the guidewire, the wall of the tube will buckle outwardly thus forming a circumferential extension 123. As with the grappling hooks 116, this circumferential extension extends radially for a distance greater than a diameter of the tube 11 but less than the expanded position of the filter or other intervascular device through which the guidewire passes. Accordingly, the filter would be prevented from traveling beyond the end of the guidewire 12 when the stop mechanism 100 is in the expanded condition. The buckle tube has a thin, flexible wall which reengages the guidewire when the buckle tube is moved axially toward the proximal end of the guidewire.

In accordance with yet another embodiment of the present invention, the stop mechanism 100 may take on the form of barbs 120 which are extendable and retractable with respect to the guidewire 12. Again a mechanism which is moved axially with respect to the guidewire 12 may be utilized in order to extend and retract the barbs 120 with respect to the guidewire 12. The barbs 120 when extended would be of a dimension greater than that of the tube 11 of the filter or intervascular device and when retracted would be permitted to readily pass through the tube 11.

The barbs 120 may be formed of spring metal with each having an end secured at 122 to the guidewire 12. These barbs, when retracted, lie within depressions 124 formed in the exterior surface of the guidewire, and when released, the spring bias of the barbs causes them to extend outwardly as shown in Figure 7. An elongate, flexible tether 126 is connected to the free end of each of the barbs 120 and passes through a hole 128 into the channel 102 in the guidewire 12. When the tethers 126 are drawn

toward the proximal end of the guidewire, the barbs 120 are retracted into the depressions 124.

In Figure 8, the stop mechanism 100 takes the form of double boss elements 130 which are spring biased with respect to the guidewire 12 and pressed outwardly by an elongate cam actuator 132 which extends axially through the channel 102 in the guidewire 12. The actuator 132 includes a chamfered cam surface 134 which cooperates with the boss elements 130 to extend such elements outwardly with respect to the guidewire 12. Again the outward extension of the boss elements would be of a dimension greater than that of the tube 11 of the filter thus preventing passage of the filter beyond the end of the guidewire 12 when the boss elements are extended.

Each boss element extends through an opening 136 in the guidewire and is attached to a mounting arm 138 secured within the channel 102. The mounting arms 138 spring bias the bosses 130 into the channel 120, but when the actuator 132 is moved toward the distal end 106 of the guidewire, the cam surface 134 forces the bosses outwardly against the spring bias through the openings 136.

I Claim:

1. In combination, a free standing, unsecured intervascular device for contact with the inner wall of a blood vessel and an elongate guidewire for extending longitudinally through and beyond said intervascular device and adapted for free longitudinal movement relative thereto, the combination comprising:

an intervascular device having a contracted configuration and an expanded configuration to an expanded outer dimension for contact with an inner wall of said blood vessel, said intervascular device including an elongate wire receiving unit having an open ended channel extending therethrough, said wire receiving unit having an outer dimension which is less than the expanded outer dimension of said intervascular device and said channel having a channel inner dimension for receiving said guidewire, and

said guidewire having an elongate flexible body extending along a longitudinal axis between a proximal end and a distal end, said flexible body having an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel in opposite directions along the longitudinal axis of said guidewire, said guidewire extending through said channel and beyond said intervascular device to position said intervascular device in spaced relationship to the proximal and distal ends of said guidewire.

2. The combination of claim 1 wherein said guidewire includes an expandable and contractable stop member mounted thereon which is movable between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensional to pass through said channel in the first contracted position thereof and being dimensioned in the second expanded position

thereof to have an outer dimension which is greater than the inner dimension of said channel but less than the outer dimension of said intervascular device in the expanded configuration thereof whereby said expandable and contractable stop member is radially spaced from the inner wall of said blood vessel in the second expanded position thereof.

3. The combination of claim 2 wherein said expandable and contractable stop member is spaced from both the proximal and distal ends of said guidewire body.

4. The combination of claim 2 wherein said expandable and contractable stop member includes a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member having a body member distal end portion secured to said guidewire and a sliding portion extending toward the proximal end of said guidewire, said sliding portion being longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause the thin walled body member to bow outwardly from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

5. The combination of claim 2 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move said expandable and contractable stop member between said first contracted and second expanded positions.

6. The combination of claim 5 wherein said guidewire body includes at least one opening formed to extend into said internal chamber, said expandable and contractable stop member including at least one stop unit retractable through said

opening into said internal chamber to the first contractable position of said expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

7. The combination of claim 6 wherein said at least one stop unit includes a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

8. The combination of claim 7 wherein said stop member operating mechanism includes an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

9. The combination of claim 8 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

10. The combination of claim 8 wherein said guidewire body includes two opposed openings into said internal chamber, and said expandable and contractable stop member includes a boss element extending through each said opening, each said boss element being secured within said internal chamber to a separate mounting arm secured to said guidewire within said internal chamber.

11. The combination of claim 10 wherein said elongate cam actuator is movable between said boss elements to engage and force said boss elements outwardly through said openings.

12. The combination of claim 11 wherein the mounting arm for each boss element is formed to bias said boss element into said internal chamber.

13. The combination of claim 6 wherein said expandable and contractable stop member includes at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

14. The combination of claim 13 wherein said strip of material is spring metal.

15. The combination of claim 13 wherein said strip of material is formed of temperature responsive shape memory material.

16. The combination of claim 5 wherein said expandable and retractable stop member includes at least one barb having a first end secured externally to said guidewire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said guidewire body including at least one opening formed to extend into said internal chamber, and said stop member operating mechanism including an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

17. The combination of claim 16 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

18. The combination of claim 2 wherein said guidewire body is formed with an internal chamber extending from the proximal end of the guidewire body toward the distal end thereof, said expandable and contractable stop member including an inflatable unit secured externally to said guidewire body, said guidewire body including at least one opening connecting said internal chamber to said inflatable unit.

19. An elongate guidewire for use with a free, unsecured intervascular device having an expanded configuration for contact with the inner wall of a blood vessel and an elongate, enclosed, open ended channel having a channel inner dimension for receiving said guidewire, said guidewire comprising:

an elongate, flexible body extending along a longitudinal axis between a proximal end and a distal end, said flexible body having an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel along the longitudinal axis of said guidewire, and

an expandable and contractable stop member mounted on said guidewire body for movement between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensioned in the first contracted position to move through said channel and being dimensioned in the second expanded position thereof to have an outer dimension which is greater than the inner dimension of said channel.

20. The combination of claim 19 wherein said expandable and contractable stop member includes a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member having a body member distal end portion secured to said guidewire and a sliding portion extending toward the proximal end of said guidewire, said sliding portion being

longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause the thin walled body member to bow outwardly from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

21. The combination of claim 19 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move said expandable and contractable stop member between said first contracted and second expanded positions.

22. The combination of claim 21 wherein said guidewire body includes at least one opening formed to extend into said internal chamber, said expandable and contractable stop member including at least one stop unit retractable through said opening into said internal chamber to the first contractable position of expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

23. The combination of claim 22 wherein said at least one stop unit includes a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

24. The combination of claim 23 wherein said stop member operating mechanism includes an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

25. The combination of claim 24 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

26. The combination of claim 22 wherein said expandable and contractable stop member includes at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

27. The combination of claim 21 wherein said expandable and retractable stop member includes at least one barb having a first end secured externally to said guide-wire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said guidewire body including at least one opening formed to extend into said internal chamber, and said stop member operating mechanism including an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

28. The combination of claim 27 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

EXHIBIT B

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NMT-010CP2 (9134/21)

The "RECEIVED" stamp of the Patent Office imprinted hereon acknowledges the filing of:

Transmittal Form (1 pg.); Fee Transmittal Form (1 pg.); Check in the amount of $519.00; Request for Continued Examination (RCE) Transmittal Form (2 pgs.); Preliminary Amendment (10 pgs.); Information Disclosure Statement (2 pgs.); Form PTO-1449 (3 pgs.), Copies of IDS Citations (A1-A44; C1-C4); and a Return Receipt Postcard, all mailed under **Express Mail Label No. EV260609491US.**

Applicants: Kleshinski

Serial Number: 09/666,452

Attys: RPMoore/ESaarmaa

Date: September 24, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Kleshinski		
SERIAL NUMBER:	09/666,452	GROUP NUMBER:	3731
FILING DATE:	September 21, 2000	EXAMINER:	Truong, Kevin Thao
TITLE:	GUIDEWIRE FOR A FREE STANDING INTERVASCULAR DEVICE HAVING AN INTEGRAL STOP MECHANISM		

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Prior to examination, please enter this Amendment and consider the accompanying remarks. Amend the application, without prejudice, as follows:

Amendments to the Claims begin on page 2 of this Amendment.

Remarks begin on page 10 of this Amendment.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims

1. (Cancelled)

2. (Currently Amended) A medical apparatus comprising:

an intervascular device ~~having~~comprising a contracted configuration and an expanded configuration, said intervascular device ~~including~~comprising an elongate wire receiving unit having an open ended channel extending therethrough for receiving a guidewire~~,~~; and,

said guidewire ~~having~~comprising an elongate body extending along a longitudinal axis between a proximal end and a distal end and an expandable and contractable stop member mounted thereon which is movable between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensioned to pass through said channel in the first contracted position ~~thereof~~ and being dimensioned in the second expanded position thereof to have an outer dimension which is greater than the inner dimension of said channel but less than the outer dimension of said intervascular device in the expanded configuration thereof, and said elongate body ~~having~~comprising an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel in opposite directions along the longitudinal axis of said guidewire.

3. (Currently Amended) The ~~combination~~apparatus of claim 2 wherein said expandable and contractable stop member is spaced from both the proximal and distal ends of said guidewire body.

4. (Currently Amended) The ~~combination~~apparatus of claim 2 wherein said expandable and contractable stop member includes a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member ~~having~~comprising a body member distal end portion secured to said guidewire and a sliding portion

extending toward the proximal end of said guidewire, said sliding portion being longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause the thin walled body member to bow outwardly from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

5. (Currently Amended) The ~~combination~~apparatus of claim 2 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move said expandable and contractable stop member between said first contracted and second expanded positions.

6. (Currently Amended) The ~~combination~~apparatus of claim 5 wherein said guidewire body ~~includes~~comprises at least one opening formed to extend into said internal chamber, said expandable and contractable stop member ~~including~~comprising at least one stop unit retractable through said opening into said internal chamber to the first contractable position of said expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

7. (Currently Amended) The ~~combination~~apparatus of claim 6 wherein said at least one stop unit ~~includes~~comprises a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

8. (Currently Amended) The ~~combination~~apparatus of claim 7 wherein said stop member operating mechanism ~~includes~~comprises an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

9. (Currently Amended) The ~~combination~~apparatus of claim 8 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

10. (Currently Amended) The ~~combination~~apparatus of claim 8 wherein said guidewire body ~~includes~~comprises two opposed openings into said internal chamber, and said expandable and contractable stop member ~~includes~~comprises a boss element extending through each said opening,

each said boss element being secured within said internal chamber to a separate mounting arm secured to said guidewire within said internal chamber.

11. (Currently Amended) The ~~combination~~apparatus of claim 10 wherein said elongate cam actuator is movable between said boss elements to engage and force said boss elements outwardly through said openings.

12. (Currently Amended) The ~~combination~~apparatus of claim 11 wherein the mounting arm for each boss element is formed to bias said boss element into said internal chamber.

13. (Currently Amended) The ~~combination~~apparatus of claim 6 wherein said expandable and contractable stop member ~~includes~~comprises at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

14. (Currently Amended) The ~~combination~~apparatus of claim 13 wherein said strip of material is spring metal.

15. (Currently Amended) The ~~combination~~apparatus of claim 13 wherein said strip of material is formed of temperature responsive shape memory material.

16. (Currently Amended) The ~~combination~~apparatus of claim 5 wherein said expandable and retractable stop member ~~includes~~comprises at least one barb having a first end secured externally to said guidewire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said guidewire body ~~including~~comprising at least one opening formed to extend into said internal chamber, and said stop member operating mechanism ~~including~~comprising an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

17. (Currently Amended) The ~~combination~~apparatus of claim 16 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

18. (Currently Amended) The ~~combination~~apparatus of claim 2 wherein said guidewire body is formed with an internal chamber extending from the proximal end of the guidewire body toward the distal end thereof, said expandable and contractable stop member ~~including~~comprising an inflatable unit secured externally to said guidewire body, said guidewire body ~~including~~comprising at least one opening connecting said internal chamber to said inflatable unit.

19. (Currently Amended) An elongate guidewire for use with a free, unsecured intervascular device ~~having~~comprising an expanded configuration for contact with the inner wall of a blood vessel and an elongate, enclosed, open ended channel ~~having~~comprising a channel inner dimension for receiving said guidewire, said guidewire comprising:

an elongate, flexible body extending along a longitudinal axis between a proximal end and a distal end, said flexible body ~~having~~comprising an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel along the longitudinal axis of said guidewire, and

an expandable and contractable stop member mounted on said guidewire body for movement between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensioned in the first contracted position to move through said channel and being dimensioned in the second expanded position thereof to ~~have~~comprise an outer dimension which is greater than the inner dimension of said channel.

20. (Currently Amended) The ~~combination~~guidewire of claim 19 wherein said expandable and contractable stop member ~~includes~~comprises a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member ~~having~~comprising a body member distal end portion secured to said guidewire and a sliding portion extending toward the proximal end of said guidewire, said sliding portion being longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause the thin walled body member to bow outwardly from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

21. (Currently Amended) The ~~combination~~guidewire of claim 19 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move said expandable and contractable stop member between said first contracted and second expanded positions.

22. (Currently Amended) The ~~combination~~guidewire of claim 21 wherein said guidewire body ~~includes~~comprises at least one opening formed to extend into said internal chamber, said expandable and contractable stop member ~~including~~comprising at least one stop unit retractable through said opening into said internal chamber to the first contractable position of expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

23. (Currently Amended) The ~~combination~~guidewire of claim 22 wherein said at least one stop unit ~~includes~~comprises a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

24. (Currently Amended) The ~~combination~~guidewire of claim 23 wherein said stop member operating mechanism ~~includes~~comprises an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

25. (Currently Amended) The ~~combination~~guidewire of claim 24 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

26. (Currently Amended) The ~~combination~~guidewire of claim 22 wherein said expandable and contractable stop member ~~includes~~comprises at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

27. (Currently Amended) The ~~combination~~guidewire of claim 21 wherein said expandable and retractable stop member ~~includes~~comprises at least one barb having a first end secured externally to said guidewire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said

guidewire body ~~including~~comprising at least one opening formed to extend into said internal chamber, and said stop member operating mechanism ~~including~~comprising an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

28. (Currently Amended) The ~~combination~~guidewire of claim 27 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

29. (New) A guidewire for introducing an intervascular device in a patient's body, comprising:

an elongate body extending along a longitudinal axis between a proximal end and a distal end; and,

an expandable and contractable stop member mounted thereon which is movable between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensioned to pass through a channel in said intervascular device in the first contracted position and being dimensioned in the second expanded position to comprise an outer dimension which is greater than the inner dimension of said channel and said elongate body comprising an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel in opposite directions along the longitudinal axis of said guidewire.

30. (New) The guidewire of claim 29 wherein said expandable and contractable stop member is spaced from both the proximal and distal ends of said guidewire body.

31. (New) The guidewire of claim 29 wherein said expandable and contractable stop member comprises a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member comprising a body member distal end portion secured to said guidewire and a sliding portion extending toward the proximal end of said guidewire, said sliding portion being longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause the thin walled body member to bow outwardly

from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

32. (New) The guidewire of claim 29 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move said expandable and contractable stop member between said first contracted and second expanded positions.

33. (New) The guidewire of claim 32 wherein said guidewire body comprises at least one opening formed to extend into said internal chamber, said expandable and contractable stop member comprising at least one stop unit retractable through said opening into said internal chamber to the first contractable position of said expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

34. (New) The guidewire of claim 33 wherein said at least one stop unit comprises a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

35. (New) The guidewire of claim 34 wherein said stop member operating mechanism compriseses an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

36. (New) The guidewire of claim 35 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

37. (New) The guidewire of claim 35 wherein said guidewire body comprises two opposed openings into said internal chamber, and said expandable and contractable stop member comprises a boss element extending through each said opening, each said boss element being secured within said internal chamber to a separate mounting arm secured to said guidewire within said internal chamber.

38. (New) The guidewire of claim 37 wherein said elongate cam actuator is movable between said boss elements to engage and force said boss elements outwardly through said openings.

39. (New) The guidewire of claim 38 wherein the mounting arm for each boss element is formed to bias said boss element into said internal chamber.

40. (New) The guidewire of claim 33 wherein said expandable and contractable stop member comprises at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

41. (New) The guidewire of claim 40 wherein said strip of material is spring metal.

42. (New) The guidewire of claim 40 wherein said strip of material is formed of temperature responsive shape memory material.

43. (New) The guidewire of claim 32 wherein said expandable and retractable stop member comprises at least one barb having a first end secured externally to said guidewire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said guidewire body comprising at least one opening formed to extend into said internal chamber, and said stop member operating mechanism comprising an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

44. (New) The guidewire of claim 43 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

45. (New) The guidewire of claim 29 wherein said guidewire body is formed with an internal chamber extending from the proximal end of the guidewire body toward the distal end thereof, said expandable and contractable stop member comprising an inflatable unit secured externally to said guidewire body, said guidewire body comprising at least one opening connecting said internal chamber to said inflatable unit.

REMARKS

Applicant has cancelled claim 1, amended claims 2-28, and added new claims 29-45. Applicant respectfully submits that no new matter has been introduced by the present Amendment. Amendments to the claims are supported by the specification at, for example, pages 11-15.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that all claims are now allowable and respectfully request allowance of claims 2-45 in due course. The Examiner is respectfully requested to telephone the undersigned at (617) 248-7044 to discuss any further issues in this matter.

Respectfully submitted,

Date: September 24, 2003
Reg. No. 44,244

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NMT-010CP2 (9134/21)

The "RECEIVED" stamp of the Patent Office imprinted hereon acknowledges the filing of the following documents:
Transmittal Form (1 pg.); Fee Transmittal Form (1 pg.); Check in the amount of $385; Request for Continued Examination Transmittal (2 pgs.); Preliminary Amendment (12 pgs.); Third Supplemental Information Disclosure Statement (2 pgs.); Third Supplemental Form PTO-1449 (1 pg.); Copies of the Cited References (A114-A121; B2-B4; and C11); and this return receipt postcard, all mailed under Express Mail Mailing Label No. EV219066622US on May 10, 2004.

Applicant:	Kleshinski
Serial No.:	09/666,452
Attorneys:	TATurano/RPMoore/KERadcliffe Sec: ajl
Date:	May 10, 2004

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EXHIBIT C

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PATENT
Attorney Docket No. NMT-010CP2
(9134/21)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Kleshinski	CONFIRMATION NO.:	1487
SERIAL NUMBER:	09/666,452	GROUP NO.:	3731
FILING DATE:	September 21, 2000	EXAMINER:	Truong, Kevin Thao
TITLE:	GUIDEWIRE FOR A FREE STANDING INTERVASCULAR DEVICE HAVING AN INTEGRAL STOP MECHANISM		

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

In response to the Notice of Allowance mailed on February 17, 2004, in connection with the above-identified patent application, Applicant respectfully submits a Request for Continued Examination and this Preliminary Amendment. A check is enclosed to pay for the Request. Applicant believes that no additional fees are due; however, in the event that additional fees are due, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 20–0531.

Prior to examination, please amend the above-identified application, without prejudice, as follows:

Amendments to the Specification begin on page 2 of this Paper;

Amendments to the Claims are reflected in the listing of claims, which begins on page 3 of this Paper; and

Remarks begin on page 12 of this Paper.

Amendments to the Specification:

Please replace the paragraph beginning at page 2, line 27, with the following paragraph:

In an attempt to contain and remove emboli and other debris, balloon angioplasty coupled with irrigation and aspiration has been performed as illustrated by U.S. Patent No. ~~5,883,644 and~~5,833,644 and International Publication No. WO 98/39046 to Zadno-Azizi et al. This procedure requires complete vessel occlusion cutting off all blood flow which imposes severe time constraints on the procedure. Additionally, the balloons involved in the procedure are affixed to elongate guidewires or small elongate catheters which extend for a substantial distance through blood vessels to the location of the stenosis or occlusion, and it is practically impossible to prevent some back and forth longitudinal motion of these elongate elements within a vessel during a procedure. This movement of the guidewire or catheter to which a balloon is attached causes the balloon to move back and forth and abrade emboli from the vessel wall downstream of the balloon containment area.

Please replace the paragraph beginning at page 3, line 11, with the following paragraph:

Angioplasty is often not a preferred treatment for lesions in the carotid artery because dislodged plaque can enter arterial vessels of the brain causing brain damage or even death. As indicated by U.S. Patent No. ~~5,879,367~~5,876,367 to Kaganov et al., carotid endarterectomy is a surgical procedure used to remove a lesion in the carotid artery, but this procedure also involves substantial risk of dislodged embolic material.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (cancelled)

Claim 2 (currently amended): A medical apparatus comprising:

an intervascular device comprising a contracted configuration and an expanded configuration, said intervascular device comprising an elongate wire receiving unit having an open ended channel extending therethrough for receiving a guidewire; and[[,]]

said guidewire comprising an elongate body extending along a longitudinal axis between a proximal end and a distal end and an expandable and contractable stop member mounted thereon which is movable between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensioned to pass through said channel in the first contracted position and being dimensioned in the second expanded position thereof to have an outer dimension which is greater than the inner dimension of said channel but less than the outer dimension of said intervascular device in the expanded configuration thereof, and said elongate body comprising an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel in opposite directions along the longitudinal axis of said guidewire.

Claim 3 (previously presented): The apparatus of claim 2 wherein said expandable and contractable stop member is spaced from both the proximal and distal ends of said guidewire body.

Claim 4 (currently amended): The apparatus of claim 2 wherein said expandable and contractable stop member ~~includes~~comprises a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member comprising a body member distal end portion secured to said guidewire and a sliding portion extending toward the proximal end of said guidewire, said sliding portion being longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause

the thin walled body member to bow outwardly from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

Claim 5 (previously presented): The apparatus of claim 2 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move said expandable and contractable stop member between said first contracted and second expanded positions.

Claim 6 (previously presented): The apparatus of claim 5 wherein said guidewire body comprises at least one opening formed to extend into said internal chamber, said expandable and contractable stop member comprising at least one stop unit retractable through said opening into said internal chamber to the first contractable position of said expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

Claim 7 (previously presented): The apparatus of claim 6 wherein said at least one stop unit comprises a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

Claim 8 (previously presented): The apparatus of claim 7 wherein said stop member operating mechanism comprises an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

Claim 9 (previously presented): The apparatus of claim 8 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

Claim 10 (previously presented): The apparatus of claim 8 wherein said guidewire body comprises two opposed openings into said internal chamber, and said expandable and contractable stop member comprises a boss element extending through each said opening, each said boss element being secured within said internal chamber to a separate mounting arm secured to said guidewire within said internal chamber.

Claim 11 (previously presented): The apparatus of claim 10 wherein said elongate cam actuator is movable between said boss elements to engage and force said boss elements outwardly through said openings.

Claim 12 (previously presented): The apparatus of claim 11 wherein the mounting arm for each boss element is formed to bias said boss element into said internal chamber.

Claim 13 (previously presented): The apparatus of claim 6 wherein said expandable and contractable stop member comprises at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

Claim 14 (previously presented): The apparatus of claim 13 wherein said strip of material is spring metal.

Claim 15 (previously presented): The apparatus of claim 13 wherein said strip of material is formed of temperature responsive shape memory material.

Claim 16 (previously presented): The apparatus of claim 5 wherein said expandable and retractable stop member comprises at least one barb having a first end secured externally to said guidewire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said guidewire body comprising at least one opening formed to extend into said internal chamber, and said stop member operating mechanism comprising an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

Claim 17 (previously presented): The apparatus of claim 16 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

Claim 18 (previously presented): The apparatus of claim 2 wherein said guidewire body is formed with an internal chamber extending from the proximal end of the guidewire body toward the distal end thereof, said expandable and contractable stop member comprising an inflatable unit

secured externally to said guidewire body, said guidewire body comprising at least one opening connecting said internal chamber to said inflatable unit.

Claim 19 (currently amended): An elongate guidewire for use with a free, unsecured intervascular device comprising an expanded configuration for contact with the inner wall of a blood vessel and an elongate, enclosed, open ended channel comprising a channel inner dimension for receiving said guidewire, said guidewire comprising:

an elongate, flexible body extending along a longitudinal axis between a proximal end and a distal end, said flexible body comprising an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel along the longitudinal axis of said guidewire, and

an expandable and contractable stop member mounted on said guidewire body for movement between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensioned in the first contracted position to move through said channel and being dimensioned in the second expanded position thereof to comprise an outer dimension which is greater than the inner dimension of said channel but less than an outer dimension of said intervascular device in the expanded configuration thereof.

Claim 20 (previously presented): The guidewire of claim 19 wherein said expandable and contractable stop member comprises a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member comprising a body member distal end portion secured to said guidewire and a sliding portion extending toward the proximal end of said guidewire, said sliding portion being longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause the thin walled body member to bow outwardly from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

Claim 21 (previously presented): The guidewire of claim 19 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move

said expandable and contractable stop member between said first contracted and second expanded positions.

Claim 22 (currently amended): The guidewire of claim 21 wherein said guidewire body comprises at least one opening formed to extend into said internal chamber, said expandable and contractable stop member comprising at least one stop unit retractable through said opening into said internal chamber to the first contractable position of said expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

Claim 23 (previously presented): The guidewire of claim 22 wherein said at least one stop unit comprises a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

Claim 24 (previously presented): The guidewire of claim 23 wherein said stop member operating mechanism comprises an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

Claim 25 (previously presented): The guidewire of claim 24 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

Claim 26 (previously presented): The guidewire of claim 22 wherein said expandable and contractable stop member comprises at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

Claim 27 (previously presented): The guidewire of claim 21 wherein said expandable and retractable stop member comprises at least one barb having a first end secured externally to said guidewire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said guidewire body comprising at least one opening formed to extend into said internal chamber, and said stop

member operating mechanism comprising an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

Claim 28 (previously presented): The guidewire of claim 27 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

Claim 29 (currently amended): A guidewire for introducing an intervascular device in a patient's body, comprising:

an elongate body extending along a longitudinal axis between a proximal end and a distal end; and[[,]]

an expandable and contractable stop member mounted thereon which is movable between a first contracted position and a second expanded position, said expandable and contractable stop member being dimensioned to pass through a channel in said intervascular device in the first contracted position and being dimensioned in the second expanded position to comprise an outer dimension which is greater than the inner dimension of said channel but less than an outer dimension of said intervascular device in an expanded configuration thereof, and said elongate body comprising an outer dimension which is less than the inner dimension of said channel to permit free movement of said guidewire relative to said intervascular device within said channel in opposite directions along the longitudinal axis of said guidewire.

Claim 30 (previously presented): The guidewire of claim 29 wherein said expandable and contractable stop member is spaced from both the proximal and distal ends of said guidewire body.

Claim 31 (previously presented): The guidewire of claim 29 wherein said expandable and contractable stop member comprises a thin walled body member mounted upon and surrounding said guidewire and dimensioned to pass with said guidewire through said channel in the first contracted position of said contractable stop member, said thin walled body member comprising a body member distal end portion secured to said guidewire and a sliding portion extending toward the proximal end of said guidewire, said sliding portion being longitudinally slidable relative to said guidewire toward the distal end of said guidewire to cause the thin walled body member to

bow outwardly from said guidewire adjacent to the body member distal end portion to form the second expanded position of said expandable and contractable stop member.

Claim 32 (previously presented): The guidewire of claim 29 wherein said guidewire is formed with an internal chamber extending from the proximal end of said guidewire toward said distal end thereof, and a stop member operating mechanism is mounted in said internal chamber to move said expandable and contractable stop member between said first contracted and second expanded positions.

Claim 33 (previously presented): The guidewire of claim 32 wherein said guidewire body comprises at least one opening formed to extend into said internal chamber, said expandable and contractable stop member comprising at least one stop unit retractable through said opening into said internal chamber to the first contractable position of said expandable and contractable stop member and extendable outwardly through said opening to the second expanded position of said expandable and contractable stop member.

Claim 34 (previously presented): The guidewire of claim 33 wherein said at least one stop unit comprises a boss element which extends through said opening and a mounting arm secured within said internal channel to said boss element and to said guidewire body.

Claim 35 (currently amended): The guidewire of claim 34 wherein said stop member operating mechanism compriseses an elongate cam actuator movable within the internal chamber to engage said stop unit and force said boss element to move outwardly through the opening in said guidewire body to the second expanded position of said expandable and contractable stop member.

Claim 36 (previously presented): The guidewire of claim 35 wherein said mounting arm is formed to bias said boss unit into said internal chamber.

Claim 37 (previously presented): The guidewire of claim 35 wherein said guidewire body comprises two opposed openings into said internal chamber, and said expandable and contractable stop member comprises a boss element extending through each said opening, each said boss element being secured within said internal chamber to a separate mounting arm secured to said guidewire within said internal chamber.

Claim 38 (previously presented): The guidewire of claim 37 wherein said elongate cam actuator is movable between said boss elements to engage and force said boss elements outwardly through said openings.

Claim 39 (previously presented): The guidewire of claim 38 wherein the mounting arm for each boss element is formed to bias said boss element into said internal chamber.

Claim 40 (previously presented): The guidewire of claim 33 wherein said expandable and contractable stop member comprises at least one elongate strip of material which engages said stop member operating mechanism within said internal chamber and is extendable thereby through said at least one opening in said guidewire.

Claim 41 (previously presented): The guidewire of claim 40 wherein said strip of material is spring metal.

Claim 42 (previously presented): The guidewire of claim 40 wherein said strip of material is formed of temperature responsive shape memory material.

Claim 43 (previously presented): The guidewire of claim 32 wherein said expandable and retractable stop member comprises at least one barb having a first end secured externally to said guidewire body, said barb being formed to normally extend from said first end angularly outward from said guidewire to a second end of said barb, said guidewire body comprising at least one opening formed to extend into said internal chamber, and said stop member operating mechanism comprising an elongate tether connected to the second free end of said barb and extending through said opening into said internal chamber.

Claim 44 (previously presented): The guidewire of claim 43 wherein said barb is formed of flexible material which biases said barb angularly outward from said guidewire body, said tether operating to draw the second end of said barb against the bias toward said guidewire body.

Claim 45 (previously presented): The guidewire of claim 29 wherein said guidewire body is formed with an internal chamber extending from the proximal end of the guidewire body toward the distal end thereof, said expandable and contractable stop member comprising an inflatable unit

secured externally to said guidewire body, said guidewire body comprising at least one opening connecting said internal chamber to said inflatable unit.

Claim 46 (previously presented): The apparatus of claim 6 wherein said stop member comprises at least one grappling hook.

Claim 47 (previously presented): The guidewire of claim 19 wherein said stop member comprises at least one grappling hook.

Claim 48 (previously presented): The guidewire of claim 29 wherein said stop member comprises at least one grappling hook.

REMARKS

Applicant hereby amends the specification to correct typographical errors. Applicant also hereby amends independent claims 2, 19, and 29, and dependent claims 4, 22, and 35. The amendments to independent claims 19 and 29 are supported by the specification at, for example, pages 9–10, by the drawings, such as FIG. 1, and by originally-filed claim 2. Independent claim 2 and dependent claims 4, 22, and 35 are amended to correct matters of form. Applicant respectfully submits that no new matter is entered by the present amendments. Upon entry of this Paper, claims 2–48 will be pending in this application.

If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues, and to work with the Examiner toward placing the application in condition for allowance.

Respectfully submitted,

Date: May 10, 2004
Reg. No. 44,244

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